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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,909

06/26/2003

Michael E. Leckrone

P0008030.03

5688

27581 7590 06/10/2009  
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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

06/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/606,909	<b>Applicant(s)</b> LECKRONE ET AL.	
	<b>Examiner</b> Darwin P. Erez	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-41 and 43-45 is/are pending in the application.  
     4a) Of the above claim(s) 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39,41 and 43-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/09 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 39, 41 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,672,158 to Okada et al. in view of US 3,645,562 to Fandetti et al. and in further view of US 1,738,996 to Hamilton et al.

Okada discloses an apparatus capable of delivering fluid device comprising: an elongated outer tubular body **33** having a lumen with an inner surface provided with an inwardly directed projection forming a ring **39**; an elongated inner tubular member **32** coaxially nested within the lumen of the outer tubular body and having an outer surface provided with outwardly directed projections forming a ring (at **40**); wherein the inwardly directed projection and the outwardly directed projection form a locking mechanism; wherein a fluid delivery catheter is slidably located to the inner tubular member (see Fig. 9; elongated dilator portion **38** is a hollow tube and is fully capable of being viewed as the fluid delivery catheter); wherein the device is capable of providing access to a pericardial space.

Okada is silent with regards to the inwardly directed projections of the elongated outer tubular body being spaced apart from one another along the circumference of the lumen; the outwardly directed projections of the elongated inner tubular body being spaced apart from one another along the circumference of the lumen; the interlocking engagement between the inwardly directed projections and the outwardly directed projections (forming the locking mechanism); wherein the elongated outer and inner tubular body have a frustoconical shape; wherein the projections from are spaced at 120 degrees from one another; and wherein a plurality of rings are provided.

However, the recited locking mechanism is well known in the coupling art. For example, Fandetti discloses a device for coupling two tubular devices, the device comprising an elongated outer tubular body **10** having a lumen with an inner surface provided with an inwardly directed projections being spaced apart from one another

along the circumference of the lumen (Fig. 2); an elongated inner tubular body **11** coaxially nested within the lumen of the outer tubular body and having an outer surface provided with outwardly directed projections being spaced apart from one another along the circumference of the lumen (Fig. 4); wherein the inwardly directed projection and the outwardly directed projection interlock to form a locking mechanism to prevent longitudinal movement of the inner tubular body within the lumen of the outer tubular body; and wherein a fluid delivery catheter is slidably located to the inner tubular body (see Fig. 9). The device of Fandetti allows for a quick connect/disconnect between the inner and outer tubular body.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the locking mechanism of Okada to have the structure taught by Fandetti because it would provide for a quick connect/disconnect means between the two tubular bodies. Furthermore, it would be obvious to substitute the locking mechanism of Okada with the locking mechanism of Fandetti because it has been held that a simple substitution for one known element for another will obtain predictable results and would be obvious to one of ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

The modified device of Okada still fails to disclose the first flange of the inner tubular member being frustoconical. However, the use of frustoconical flanges in tubular connectors are well known in the art, as disclosed by Hamilton et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Okada to have frustoconical flanges because the use

of connectors having frustoconical shape is well known in the art. Furthermore, it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

With regards to the projections being spaced at 120 degrees from one another, it would have been an obvious matter of design choice to modify the projections to be spaced at 120 degrees from one another since applicant has not disclosed that the projections being spaced apart 120 degrees solves any stated problem or is used for any particular purpose. Furthermore, one of ordinary skill in the art would have expected Okada's apparatus to perform equally as well with the projections at 120 degrees. Again, it is noted that limitations in the claim which presents no novel or unexpected result over a similar feature used in the prior art references, and solved no stated problem, were held to be an obvious matter of design choice within the skill of the art. *In re Kuhle*, 526 F.2d 523; 188 USPQ 7 (CCPA 1975). *In re Gazda*, 42 CCPA 770; 219 F.2d 449; 104 USPQ 400 (1955). *In re Launder*, 42 CCPA 886; 222 F.2d 371; 10 USPQ 446 (1955).

With regards to the apparatus having a plurality of rings, it would have been obvious to one of ordinary skill in the art to modify the apparatus to have a plurality of rings instead of a single ring since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d, 669, 124 USPQ 378 (CCPA 1960).

***Response to Arguments***

5. Applicant's arguments filed 3/23/09 have been fully considered but they are not persuasive.

The applicant argued that Okada fails to teach an elongated outer tubular body. However, this limitation is not persuasive as the term "elongated" does not imply a specific length for the structure. The claim limitations also does not preclude the examiner from interpreting the entire element 33 as the elongated outer tubular body as the claim merely requires that the elongated outer tubular body has a lumen, and wherein the inner tubular member is nested within this lumen. The claim does not specify that the lumen has to extend from the proximal end to the distal end defining a length therebetween, and wherein the inner tubular member is nested within the entire length of the lumen of the elongated outer tubular member.

As discussed with the applicant's representative, Carol Barry, on 6/4/09, the examiner suggests to amend claim 1 to clearly define a length for the lumen of the outer tubular body and that the inner tubular member is nested within the entire length of this lumen.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/  
Primary Examiner, Art Unit 3773